compounds that deliver the present benefit and those that do not. Unfortunately, this assertion is not supported by any facts. The Applicant concedes that these terms encompass more than a few chemical species, and it seems logical that some of these individual species will provide better efficacy than others. But it does not follow that there are species that provide no benefit whatsoever. If the Examiner is aware of any published medical or scientific evidence to support this assertion the Applicant would be most interested in reviewing such data. Moreover, this rejection assumes an unstated and apparently arbitrary standard for efficacy, which makes it difficult to refute the present rejection. As such, the Applicant respectfully requests that the Examiner supply support for this rejection the form of published data proving the lack of efficacy for specific chemical species with the claimed families of chemical. Absent such proof, the Applicant respectfully requests that this rejection be reconsidered and withdrawn.

Claims 1, 13, 22, and 34 stand rejected under § 112, second paragraph, for being allegedly indefinite for the use of the term "precursors", and claims 13 and 34 are further rejection for the use of the term "substantially". The Applicant respectfully traverses these rejections because these terms do not necessarily render the claims indefinite. The fact that claim language, including terms of degree, may not be precise, does not automatically render the claim indefinite under 35 USC § 112, second paragraph. *Seattle Box Co., v. Industrial Crating and Packing, Inc.*, 731 F.2d 818, (Fed.Cir. 1984). Acceptability of the claim language depends on whether one of ordinary skill in the art understands what is claimed, in light of the specification. The terms "substantially" and "precursors" are notoriously well known in the art, and to the extent there is any ambiguity regarding the use of these terms in the claims, these terms are fully defined in the specification.

More specifically, the term "substantially" in claims 13 and 34 is used in the context of "substantially free of Aspartame". Those skilled in the art of formulating compositions for human consumption will know how to formulate a composition without using Aspartame. Moreover, because Aspartame is not a naturally occurring compound, it is easy to avoid. That is, very few raw materials contain Aspartame so the only way for it to enter a composition is for the formulator to add it intentionally. To the extent this is not clear, the specification provides further guidance in the second full paragraph of page 14. In this paragraph, specific limits that constitute "substantially free of" are given. As stated above, the standard for definiteness is the understanding of one skilled in the art in light of the specification. The term "substantially" in the claims is not indefinite to one skilled in the art, and even if it were, the description of this term in the specification removes any question regarding the limits of this term.

Likewise, the term "precursors", as used in the present claims, will be clear to those skilled in the art, in light of the present specification. A precursor is a well known chemical quantity, and the term precursor is not used alone in the present claims but in the context of "precursors of methylsulfonylmethane". A modifying and descriptive term such as precursor must be read in context when determining its definiteness. In this particular case, the term precursor is used in a relatively

limited context and would be definite to those skilled in the art. But even if there were some question regarding this term, the specification clearly defines the context of this term. Specifically, in the fourth full paragraph on page 11 of the present specification, a definition and examples are given that fully defines "precursors of methylsulfonylmethane". Moreover, US Patent No. 4,863,748, is incorporated by reference (on page 4) and gives even further details and examples of "precursors of methylsulfonylmethane". As such, those skilled in the art, with reference to the present specification, would find the term "precursors of methylsulfonylmethane" definite as used in the present claims. Because the specification provides more than enough information regarding the terms "substantially" and "precursors" it is believed that these terms are definite when read by one skilled in the art in light of the specification. And the present rejection of these terms under § 112, second paragraph, should be withdrawn.

Claims 1, 13, 22, and 34 have been rejected because of the negative limitation that begins with "other than". By the present amendment, the term "other than" has been eliminated from the claims. As such, the present rejection is believed to be obviated, and the Examiner is respectfully requested to withdraw this rejection.

Finally, claims 5, 6, 17 and 18 stand rejected because they include subject matter that was excluded in the claims from which they depend. Without address the merits of this rejection, claims 5, 6 17 and 18 have all been cancelled by the present amendment. As such, the present rejection is believed to be obviated and the Examiner is respectfully requested to withdraw this rejection.

Provisional Obviousness-type Double Patenting Rejections

Claims 1-50 have been provisionally rejected over US Patent Applications 09/760,280, 09/586,520, 09/586,284, and 09/586,514. The Applicant is aware of these co-pending applications, but none of the claims of these applications have been granted. Without addressing the merits of this rejection, the Applicant acknowledges the rejections, but defers a substantive response until the claims of the present application, or the claim of one or more of the referenced co-pending applications are granted. If, after prosecution and grant of this case and the allowance of one or more of the referenced applications, the Examiner maintains the present obviousness-type double patenting rejection then the Applicant will file a Terminal Disclaimer if necessary and appropriate.

Rejection under 35 USC § 103(a)

Claims 1-50 stand rejected under 35 USC § 103 for allegedly being obvious in light of 17 different references supplied by the Applicants in the Information Disclosure Statement, and an additional 4 references supplied by the Examiner. Without reference to any specific passages in the 21 different references cited against the present claims, the Official Action states that the individual ingredients, the compositions and the administration thereof are all well known in the prior art. The Applicant respectfully traverses this rejection.

The present invention is directed to compositions and kits that contain a chondroprotective agent that is selected from the group consisting of cartilage, aminosugars, glycosaminoglycans, methylsulfonylmethane, precursors of methylsulfonylmethane, S-adenosylmethionine, and mixtures thereof. Some of the compositions and kits further comprise a sweetening agent selected from the group consisting of sorbitol, mannitol, xylitol, erythritol, malitol, maltose, lactose, fructooligosaccharides, lo han guo, stevioside, acesulfame, sucralose, saccharin, xylose, arabinose, levulose, isomalt, ribose and mixtures thereof and at least about 10% water, by weight of the composition. In addition to these sweeteners, some of the compositions of the present invention comprise Aspartame. And in addition to the chondroprotective agent defined above, some of the compositions and kits contain less than about 19 grams total carbohydrate per every 230 milliliters of the composition. The compositions of the present invention provide a substantial benefit over compositions of the prior art in that they are easily administered orally and are low calorie, and have a low sugar content. Moreover, the chondroprotective agent provides a substantial medical benefit by improving tissue within the joints of the person who takes the compositions herein. Thus, the present compositions provide a medical benefit, they are easier to take, and they do not have an adverse effect on the recipient's blood sugar. When viewed as a whole, the present invention provides substantial benefits over the teachings of the prior art, and as such, is not obvious over prior art teachings.

As mentioned briefly above, there are no specific passages referenced in the 21 citations relied upon by the Examiner in support of this rejection (to be accurate, there are only 20 citations as AZ and A in the official Action refer to the same US Patent). Rather, only a blanket assertion is made that the present compositions are known. This is not an accurate representation of the present claims as amended herein. Nor has the Examiner met his burden of establishing a *prima facie* case of obviousness, which requires the establishment of three basic criteria. First, there must be some suggestion or motivation either in the references themselves or in the knowledge generally available to the one of ordinary skill in the art to modify the reference or to combine reference teachings. See, for example, *In re Fine*, 837 F.2d 1071, (Fed.Cir. 1998), and *In re Jones*, 958 F.2d 347, (Fed.Cir. 1992). Second, there must be a reasonable expectation of success. And finally, the prior art references, (or references when combined) must teach or suggest all of the claim limitations. See, for example, *In re Veack*, 947 F.2d 488, (Fed.Cir. 1991).

The Official Action fails to establish any one of these three criteria. It is arguably true that certain ingredients in the claims may be known to the art, but the present invention is more than a list of ingredients. And citing 20 random references that may or may not be relevant to the patentability of the present invention, does not meet the burden placed on the Patent Examiner to establish the three criteria that establish a *prima facie* case of obviousness. A statement that modifications of the prior art to meet the claimed invention would have been "well within the ordinary skill of the art at the time the claimed invention was made" because the references relied upon teach all aspects of the claimed invention were individually known in the art is <u>not</u> sufficient to establish a *prima facie* case of

obviousness without some objective reason to combine the teachings of the references. *Ex parte Levengood*, 28 USPQ2d 1300, (Bd.Pat.App..&Inter. 1993). The Official Action fails to establish any such "objective reason" why the 20 references should be combined, or how they should be combined. As such, a case of *prima facie* obviousness has not been made.

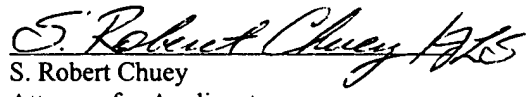
Moreover, this rejection ignores the purpose and benefits of the present invention. The present compositions and kits provide the joint improving benefits from the chondroprotective agent in an easily administered form that is low calorie and does not have a substantial impact on the recipients blood sugar as does a composition high in natural sugar, carbohydrates and calories in general. The present compositions and kits, as amended herein are not found in the prior art, nor would they be obvious over the broad and general teachings of the 20 references relied upon by the Examiner. As such, the Applicant respectfully requests that the rejection of the present claims under § 103 be withdrawn.

CONCLUSION

Attached hereto is a marked-up version of the changes made to the specification and claims by the current amendment. The attached page is captioned **"Version with markings to show changes made."**

In light of the amendments to the claims and the above remarks, it is requested that the Examiner reconsider and withdraw the rejections under 35 USC §§ 101, 112, 103(a) and the Provisional Obviousness-type Double Patenting rejections. Early and favorable action in the case is respectfully requested.

Respectfully submitted,



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Date: April 30, 2002

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

1. (Amended) A composition comprising:
   a) a chondroprotective agent selected from the group consisting of ~~gelatin,~~ cartilage, aminosugars, glycosaminoglycans, methylsulfonylmethane, precursors of methylsulfonylmethane, S-adenosylmethionine, and mixtures thereof;
   b) a sweetening agent ~~other than glucose, dextrose, sucrose, and fructose~~ selected from the group consisting of sorbitol, mannitol, xylitol, erythritol, malitol, maltose, lactose, fructooligosaccharides, lo han guo, stevioside, acesulfame, aspartame, sucralose, saccharin, xylose, arabinose, levulose, isomalt, ribose and mixtures thereof; and
   c) at least about 10% water, by weight of the composition.

2. A composition according to Claim 1 wherein the chondroprotective agent is selected from the group consisting of aminosugars, glycosaminoglycans, S-adenosylmethionine, and mixtures thereof.

3. Claim 3 has been canceled.

4. (Amended) A composition according to Claim ~~3~~2 wherein the chondroprotective agent is selected from the group consisting of aminosugars, glycosaminoglycans, and mixtures thereof and wherein:
   a) the aminosugars are selected from the group consisting of glucosamine and salts thereof; and
   b) the glycosaminoglycans are selected from the group consisting of chondroitin and salts thereof.

5. Claim 5 has been canceled.

6. Claim 6 has been canceled.

7. A composition according to Claim 4 wherein the sweetening agent is selected from the group consisting of xylitol, erythritol, fructooligosaccharides, lo han guo, stevioside, acesulfame, aspartame, sucralose, and mixtures thereof.

8. A composition according to Claim 7 wherein the sweetening agent is selected from the group consisting of erythritol, sucralose, and mixtures thereof.

9. A composition according to Claim 8 further comprising one or more beverage components selected from the group consisting of fruit juice, tea, milk solids, and mixtures thereof.

10. A composition according to Claim 9 comprising at least about 75% water, by weight of the composition.

11. A composition according to Claim 10 further comprising one or more nutrients.

12. A composition according to Claim 10 further comprising one or more omega-3-fatty acids.

13. (Amended) A composition comprising:

a) a chondroprotective agent selected from the group consisting of ~~gelatin~~, cartilage, aminosugars, glycosaminoglycans, methylsulfonylmethane, precursors of methylsulfonylmethane, S-adenosylmethionine, salts thereof, and mixtures thereof; and

b) a sweetening agent ~~other than glucose, dextrose, sucrose, and fructose~~ selected from the group consisting of sorbitol, mannitol, xylitol, erythritol, malitol, maltose, lactose, fructooligosaccharides, lo han guo, stevioside, acesulfame, sucralose, saccharin, xylose, arabinose, levulose, isomalt, ribose and mixtures thereof;

wherein the composition is substantially free of aspartame.

14. A composition according to Claim 13 wherein the chondroprotective agent is selected from the group consisting of aminosugars, glycosaminoglycans, S-adenosylmethionine, and mixtures thereof.

15. Claim 15 has been canceled.

16. (Amended) A composition according to Claim 1~~5~~3 wherein the chondroprotective agent is selected from the group consisting of aminosugars, glycosaminoglycans, and mixtures thereof and wherein:

c) the aminosugars are selected from the group consisting of glucosamine and salts thereof; and

d) the glycosaminoglycans are selected from the group consisting of chondroitin and salts thereof.

17. Claim 17 has been canceled.

18. Claim 18 has been canceled.

19. (Amended) A composition according to Claim 16 wherein the sweetening agent is selected from the group consisting of xylitol, erythritol, fructooligosaccharides, lo han guo, stevioside, acesulfame, ~~aspartame~~, sucralose, and mixtures thereof.

20. A composition according to Claim 19 wherein the sweetening agent is selected from the group consisting of erythritol, sucralose, and mixtures thereof.

21. A composition according to Claim 20 further comprising one or more beverage components selected from the group consisting of fruit juice, tea, milk solids, and mixtures thereof.

22. A composition comprising:
    a) a chondroprotective agent selected from the group consisting of gelatin, cartilage, aminosugars, glycosaminoglycans, methylsulfonylmethane, precursors of methylsulfonylmethane, S-adenosylmethionine, salts thereof, and mixtures thereof;
    b) at least about 10% water, by weight of the composition; and
    c) less than about 19 grams total carbohydrate per every 230 milliliters of the composition.

23. A composition according to Claim 22 wherein the chondroprotective agent is selected from the group consisting of aminosugars, glycosaminoglycans, S-adenosylmethionine, and mixtures thereof.

24. A composition according to Claim 23 comprising a sweetening agent selected from the group consisting of sorbitol, mannitol, xylitol, erythritol, malitol, maltose, lactose, fructooligosaccharides, lo han guo, stevioside, acesulfame, aspartame, sucralose, saccharin, xylose, arabinose, levulose, isomalt, and ribose.

25. A composition according to Claim 24 wherein the chondroprotective agent is selected from the group consisting of aminosugars, glycosaminoglycans, and mixtures thereof and wherein:

a) the aminosugars are selected from the group consisting of glucosamine and salts thereof; and

b) the glycosaminoglycans are selected from the group consisting of chondroitin and salts thereof.

26. A composition according to Claim 25 further comprising at least one sweetener selected from the group consisting of sucrose, fructose, and mixtures thereof.

27. A composition according to Claim 26 further comprising a caloric sweetener selected from the group consisting of glucose, dextrose, sucrose, fructose, and mixtures thereof.

28. A composition according to Claim 27 comprising less than about 18.5 grams total carbohydrate per every 230 milliliters of the composition.

29. A composition according to Claim 28 further comprising one or more beverage components selected from the group consisting of fruit juice, tea, milk solids, and mixtures thereof.

30. A composition according to Claim 28 comprising less than about 18 grams total carbohydrate per every 230 milliliters of the composition.

31. A composition according to Claim 30 comprising at least about 75% water, by weight of the composition.

32. A composition according to Claim 31 further comprising one or more nutrients.

33. A composition according to Claim 31 further comprising one or more omega-3-fatty acids.

34. A composition comprising:

a) a chondroprotective agent selected from the group consisting of gelatin, cartilage, aminosugars, glycosaminoglycans, methylsulfonylmethane, precursors of methylsulfonylmethane, S-adenosylmethionine, salts thereof, and mixtures thereof; and

b) less than about 18 grams total carbohydrate per every 230 milliliters of the composition;

wherein the composition is substantially free of aspartame.

35. A composition according to Claim 34 wherein the chondroprotective agent is selected from the group consisting of aminosugars, glycosaminoglycans, S-adenosylmethionine, and mixtures thereof.

36. (Amended)A composition according to Claim 35 comprising a sweetening agent selected from the group consisting of sorbitol, mannitol, xylitol, erythritol, malitol, maltose, lactose, fructooligosaccharides, lo han guo, stevioside, acesulfame, ~~aspartame~~, sucralose, saccharin, xylose, arabinose, levulose, isomalt, and ribose.

37. A composition according to Claim 36 wherein the chondroprotective agent is selected from the group consisting of aminosugars, glycosaminoglycans, and mixtures thereof and wherein:
    a) the aminosugars are selected from the group consisting of glucosamine and salts thereof; and
    b) the glycosaminoglycans are selected from the group consisting of chondroitin and salts thereof.

38. A composition according to Claim 37 further comprising at least one sweetener selected from the group consisting of sucrose, fructose, and mixtures thereof.

39. A composition according to Claim 38 further comprising a caloric sweetener selected from the group consisting of glucose, dextrose, sucrose, fructose, and mixtures thereof.

40. A composition according to Claim 39 comprising less than about 18.5 grams total carbohydrate per every 230 milliliters of the composition.

41. A composition according to Claim 40 further comprising one or more beverage components selected from the group consisting of fruit juice, tea, milk solids, and mixtures thereof.

42. A composition according to Claim 41 comprising less than about 18 grams total carbohydrate per every 230 milliliters of the composition.

43. A kit comprising:
    (a) a composition according to Claim 1; and

(b) information that use of the composition is useful for one or more benefits selected from the group consisting of joint health benefits, bone health benefits, anti-inflammation, and utility for diabetic mammals.

44. A kit comprising:

(a) a composition according to Claim 13; and

(b) information that use of the composition is useful for one or more benefits selected from the group consisting of joint health benefits, bone health benefits, anti-inflammation, and utility for diabetic mammals.

45. A kit comprising:

(a) a composition according to Claim 22; and

(b) information that use of the composition is useful for one or more benefits selected from the group consisting of joint health benefits, bone health benefits, anti-inflammation, and utility for diabetic mammals.

46. A kit comprising:

(a) a composition according to Claim 34; and

(b) information that use of the composition is useful for one or more benefits selected from the group consisting of joint health benefits, bone health benefits, anti-inflammation, and utility for diabetic mammals.

47. A method of treating a condition selected from the group consisting of joint dysfunction, bone dysfunction, and inflammation comprising orally administering to a mammal a composition according to Claim 1.

48. A method of treating a condition selected from the group consisting of joint dysfunction, bone dysfunction, and inflammation comprising orally administering to a mammal a composition according to Claim 13.

49. A method of treating a condition selected from the group consisting of joint dysfunction, bone dysfunction, and inflammation comprising orally administering to a mammal a composition according to Claim 22.

50. A method of treating a condition selected from the group consisting of joint dysfunction, bone dysfunction, and inflammation comprising orally administering to a mammal a composition according to Claim 34.